In view of the amendments to claim 49, claims 53 and 54 have also been canceled.

Claims 63-78 have also been canceled.

Applicants note that claim cancellations have been made without waiver or prejudice to their right to file one or more divisional or continuation applications directed to canceled subject matter.

Claims 49-58 and 62 continue to be rejected under 35 USC 102(b) as being anticipated by Kerc, WO 96/36318. The examiner commented as follows:

> Kerc discloses a pharmaceutical composition comprising a core, and a coating surrounding the core (page 4, 1st and 2nd paragraphs). The core comprises an amorphous drug dispersed in a polymer such as polyvinyl pyrrolidone and hydroxypropylmethyl cellulose with a viscosity from 3-1500 mPa.s (page 7; and example 1). The core is further mixed with excipients including cellulose ethers, glidant, filler, and lubricant (osmotic agent and osmotically effective solute) (page 8, 2nd-3rd paragraph; page 9, 1st-2nd paragraph; and page 10, last paragraph through page 11, 2nd-3rd paragraph). The core is then coated with a film coating (page 9, paragraph 3 through page 10; page 11, paragraphs 2-3). Drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4th paragraph. The composition can be prepared in granule (multiparticulate) form, the granule can then be compressed into tablet, and the tablet is coated with a film (page 11; and examples).
>
> It is noted that Kerc does not explicitly teach at least one delivery port. However, it is the position of the examiner that the exit port is an inherent feature, because Kerc teaches the use of the same drug (amorphous agent), the same osmotic agent (hydroxyethyl cellulose, hydroxypropyl cellulose, or hydroxypropylmethyl cellulose), the same osmotically effective solute (mannitol, sorbitol, glucose, or sodium chloride), the same dispersing polymer (hydroxypropylmethyl cellulose), and the same water-permeable coating. Accordingly, the water-permeable coating of the same polymer would have the same properties, e.g., porous (delivery ports). Applicant's specification at page 23, lines 16-29, and page 24, lines 13-22, defines delivery ports as any opening or pores that are formed *in situ* during use. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, when the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

As a preliminary matter it is noted that the rejection is moot in respect of claims 63-78 since these claims have been canceled. The rejection is otherwise traversed, *inter alia*, on the basis that Kerc does not disclose a controlled release dosage form having a core with a drug layer composition and a sweller layer composition arranged in a bi-layer geometry. For this reason alone, Kerc does not disclose all elements of Applicants' invention, hence cannot anticipate. In addition, it is noted that none of the dispersion polymers now required by Applicants is disclosed in Kerc.

Kerc discloses a coated matrix delivery system comprising a core of drug-containing granules that also comprise a controlled release matrix, the core having a

coating surrounding it as a "third phase". Both polymers listed as suitable for use in the Kerc's coating (see Kerc at page 9) are enteric, meaning that they dissolve once the dosage form has passed the upper GI tract and reached the higher pH region of the lower GI tract. Kerc himself describes the coating as being "...poorly soluble or gastro-resistant ...for additional delay in release" illustrating the coating's clear function in delaying release until the dosage form is past the upper GI tract. Kerc's disclosure is thus related to an altogether different controlled release dosage form than Applicants' osmotic dosage form. Because Kerc's coatings are enteric and dissolve in the higher pH environment of the lower GI tract, they are not "non-dissolving and non-eroding during release of said drug", as required by Applicants.

Further, because Kerc does not relate to osmotic dosage forms, Kerc does not disclose a delivery port of any type, as required elements in Applicants' claims. Indeed, it would make no sense for Kerc to disclose a port since that would defeat the purpose of his invention, this being discussed further below.

The Examiner's argument that a port is inherent is noted and traversed. Ports can be implemented in osmotic dosage forms by (1) physical means, for example by physically laser drilling through a tablet coating (2) forming the pore during the coating process, or (3) forming the port *in situ* during use. See Applicants' specification at pages 23-24 where pore formation is discussed extensively. Under inherency law a result, in this case port formation, must be inevitable. Thus a rejection grounded in inherency requires that a port would inevitably or necessarily be formed in the Kerc dosage forms. The law on this is well established as Applicants discuss below.

Inherency will not lie because Kerc never discloses forming a port or any means for forming one. Kerc never mentions the word "port", never discloses forming an orifice in his coating, and never discloses any means for doing so. Importantly, implementing a port in Kerc would negate his invention. To repeat, both polymers listed as suitable for use in Kerc's coating (see Kerc at page 9) are enteric, meaning that they dissolve once the dosage form has passed the upper GI tract and reached the lower (higher pH) GI tract. Kerc's description of his polymer film coating as being "...poorly soluble or gastro-reistant ...for additional delay in release" illustrates his purpose of delaying release. Implementing a delivery port in Kerc as required by Applicants would immediately (i.e., upon swallowing) defeat that purpose by exposing Kerc's core to the GI environment.

In addition to the fact that ports are not inherent (and would in fact be undesirable) in Kerc, Applicants note the requirement that their coating be non-dissolving and non-eroding during release of the drug. A coating that is "non-dissolving and non-eroding during release" is an additional element not disclosed in Kerc, whose invention would be inoperable if his coating were non-dissolving and non-eroding. Kerc provides a coating that delays release, not one that prevents it altogether. Kerc's coating must

dissolve as pH increases along the GI tract in order for his dosage form to release drug. Applicants' non-eroding and non-dissolving coating would prevent Kerc from releasing any drug at all.

Another contention raised by the Examiner pursuant to the anticipation rejection over Kerc is that chemical compositions must be the same if they contain the same chemical "structure". Office Action, page 7, 3rd to 9th lines from the bottom:

> Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 f.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The Examiner's comments are traversed. It is indeed possible for compositions to contain the same components and yet be different due to the fact that they differ structurally. The Spada case is inapposite as it did not deal with dosage forms that are physically structurally different. Spada dealt with a claimed polymer and a prior art polymer that appeared to be derived from the same monomers. Applicants note it is very possible for two compositions, i.e., dosage devices, to contain the same components but to differ structurally and thereby function by different mechanisms and/or in different manners. To give an analogy, chocolate cakes and chocolate chip cookies contain many of the same ingredients, but they have different structures such that nobody would contend that they are the same. Extending the analogy to the instant facts, enteric polymers are known for use as coatings that resist degradation in the low pH (acid) environment of the upper GI tract but that readily dissolve in the higher pH environment of the lower GI tract. That is the fashion in which they are employed in Kerc. Enteric polymers applied as coatings are designed to protect the dosage form core during transit through the low pH environment of the upper GI tract and to dissolve once having passed into the higher pH environment of the lower GI tract. But, Kerc's dosage form is not osmotic and, without a port, will not function as an osmotic dosage form regardless of the ingredients in its core. The Examiner has provided no basis that Kerc contains a port formed by any means, and Kerc himself never mentions port formation.

From a legal perspective, the inherency standard is an exacting one, one that Kerc does not meet:

> Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is "necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill."

Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002) (citations omitted).

Furthermore,

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In respect of the instant §102 rejection, the Examiner has provided no basis that a port would ever be formed in Kerc, let alone that it would necessarily be formed, as inherency requires. And, for the reasons discussed above, it makes no sense that Kerc would want to form a port in his device since a port would defeat its operation.

It is well accepted that the standard for anticipation is one of strict identity, meaning that for prior art to anticipate, it must contain all of the essential elements. Hybritech Inc. v. Monoclonal Antibodies, Inc.231 USPQ 81 (Fed Cir 1986). See In re Donohue, 226 USPQ 619 (Fed Cir 1985) where it was stated:

> an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.

Clearly, and especially considering Applicants' claims as currently amended, Kerc does not disclose all of the elements in Applicants' claims, whether or not inherency is invoked. Essentially the whole of Applicants' subparagraph (b) of independent claim 49 is missing from Kerc, plus the requirement of having a bi-layer construction. More specifically, Kerc does not disclose the following elements required by Applicants:

1. That the dosage form is an osmotic dosage form;

2. A core having a drug layer composition and a sweller layer composition in a bi-layer geometry;

3. The drug is in the drug layer and the osmotic agent is in the sweller layer;

4. A port for drug release (which would in fact defeat Kerc's purpose of delaying release), noting also that no basis for alleging inherency exists.

5. A coating that is non-eroding and non-dissolving during release. Kerc in fact discloses the opposite. Kerc's coating, being enteric, dissolves and releases in the lower GI tract.

Accordingly, withdrawal of the anticipation rejection over Kerc is accordingly respectfully requested.

Claims 49-58 and 60-62 were rejected under 35 USC 103(a) over Faour, US 6,004,582 in view of Kerc. The Examiner relied upon Kerc for the reasons previously stated in the Office Action. The Examiner appeared to be relying on Faour because it discloses an osmotic device. The Examiner commented in pertinent part as follows:

> Faour teaches an osmotic device comprising a core comprises an active agent, an osmotic agent and polyvinyl pyrrolidone; a semi-permeable membrane; and a passage way (column 4, lines 63 through column 5, lines 1-30; and column 9, lines 52-58). Active agent is disclosed in columns 14-15. Semi-permeable membrane is made of material that remains its chemical and physical integrity in

the environment of use (column 9, lines 1-16). The core further includes osmotically effective solutes (column 9, lines 38-51). Faour further teaches the use of tablet binder such as polyvinyl pyrrolidone, cellulose material, polypropylene glycol, and polyoxyethylene-polyoxyproprylene copolymer (column 10, lines 35-57).

Faour does not explicitly teach solid dispersion of a drug in its amorphous form. However, Kerc teaches dispersing an amorphous active agent in polymers is especially suitable for active agents which exhibit poor solubility in crystal form (abstract). Thus, it would have been obvious to one of ordinary skill in the art to prepare the osmotic device of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kerc, because Kerc teaches using amorphous active agent in which the solubility and the dissolution rate of the active agent will be independent of its polymorphous form, crystallinity, particle size and specific surface area, because Kerc teaches crystalline active agents have the essential disadvantage due to the presence of the crystalline in several polymorphous modification, crystal size, and results in a release rate that is not constant, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

The rejection is traversed on the basis that the references, Faour and Kerc, are not properly combinable. Kerc, as noted above, relates to a matrix controlled release dosage form having a specific geometry, not to an osmotic one. The Examiner has provided no basis as to how or why, absent Applicants' specification, the Kerc reference relating to a matrix controlled release device should be combined with the Faour reference relating to an osmotic dosage form, a device that differs from Kerc in structure and mechanism of delivery. Applicants respectfully submit that the combination is arbitrary because osmotic devices like the one in Faour operate by a mechanism (extrusion of drug composition through a port) different from and unrelated to matrix controlled release devices like the one in Kerc (release from a matrix after dissolution of a surrounding membrane in the lower GI tract). The operation and mechanisms of release are completely different. For that reason one of ordinary skill in the art would not find it obvious to combine the references, particularly as the Examiner has done, i.e., by inserting a piece from one reference (a dispersion from Kerc) into the unrelated osmotic dosage form of Faour.

Applicants accordingly submit that the Examiner has provided no basis supporting the combination of Faour and Kerc.

Claims 49-62 were rejected under 35 USC 103(a) as being unpatentable over Faour et al., in view of Kigoshi et al. US 6,254,889. Faour was relied upon for the reasons disclosed in the Faour v. Kerc rejection. The Examiner noted that Faour does not explicitly teach solid dispersions of a drug in its amorphous form, as well as the use of a specific dispersion polymer such as hydroxypropylmethyl cellulose acetate succinate.

The Examiner further stated, in pertinent part, that

Kigoshi teaches a solid dispersion dosage form of a slightly soluble drug comprising dispersing an amorphous drug in a dispersion polymer including hydroxypropylmethyl cellulose acetate succinate (see abstract; and column 3, lines 18-33). The dispersing solution is sprayed onto an absorbent carrier to obtain a drug core. The core is than mixed with excipient, and made into dosage form (column 4, lines 39-67). Thus, it would have been obvious to one of ordinary skill in the art to prepare the drug core of Faour using the solid dispersion of an amorphous drug in view of the teaching of Kigoshi, because Kigoshi teaches slightly soluble drugs have high crystallinity and low bioavailability, because Kigoshi teaches improving the solubility and bioavailability of slightly soluble drugs by dispersing slightly soluble drug in a polymer to form a solid dispersion, because Faour teaches the use of poorly soluble drugs, and because Faour teaches the osmotic device can be prepared according to methods known in the art.

The above discussion relating to Faour v. Kerc is equally applicable to Faour v. Kigoshi. Kigoshi discloses dispersions of xanthines. Faour relates to an osmotic device. Considering Faour, Kigoshi, and Applicants' specification, the only disclosure relating to employing a solid amorphous dispersion in a controlled release device of any type is Applicants'. There is no disclosure in either Faour or Kigoshi that would lead one of ordinary skill in the art to modify the teachings of the other in such a way as to combine a dispersion like those disclosed in Kigoshi with an osmotic delivery device. Only Applicants have disclosed such an embodiment in the instant application, but Applicants' specification may not be used as prior art against them. Kigoshi simply discloses that some of the polymers useful as dispersion polymers in Applicants' invention are known. Faour simply discloses an osmotic dosage form with no disclosure of improving the solubility of the drug therein. There is no reason as between Faour and Kigoshi that would lead one of ordinary skill in the art to modify the teachings of either in according with the teachings of the other.

It is accordingly respectfully submitted that the rejection of claims 49-78 over Faour in view of Kigoshi should be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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